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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 254,617	03 22 1999	JACQUES MALLET	ST96025-US	7283

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WILEY, REIN & FIELDING, LLP  
INTELLECTUAL PROPERTY DEPARTMENT  
1776 K. STREET N.W.  
WASHINGTON, DC 20006

EXAMINER
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BAKER, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12 31 2001

# 13

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/254,617	MALLET ET AL.	
	Examiner	Art Unit	
	Anne-Marie Baker	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 October 2001.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 26-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 26-51 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 22 March 1999 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

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## **DETAILED ACTION**

The amendment filed October 23, 2001 (Paper No. 11) has been entered. Claim 49 has been amended.

Accordingly, Claims 26-51 remain pending in the instant application.

The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-35, 37-42, 44, 45, 49, 50, and 51 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating amyotrophic lateral sclerosis (ALS) comprising systemic administration of a pharmaceutical composition comprising an adenoviral vector encoding a neurotrophic factor and a pharmaceutical composition comprising two adenoviral vectors encoding two neurotrophic factors, does not reasonably provide enablement for a method of treating ALS by administering any type of vector encoding a neurotrophic factor or a pharmaceutical composition comprising any type of vector encoding a neurotrophic factor. The specification does not

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

At page 3 of the response, Applicants argue that the rejection set forth is grounded on a “degree of effectiveness” rationale. However, this is not the case, as the specification only teaches how to practice the claimed invention using adenoviral vectors, and does not provide specific guidance for protocols using other types of vectors, such that a specific therapeutic effect would be produced, i.e. treatment of amyotrophic lateral sclerosis. Thus, undue experimentation would have been required to carry out the claimed method and use the claimed compositions over the full scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26-51 are indefinite in their recitation of “expression system” because the use of the term in the claims is in direct conflict with the definition of the term in the specification. The specification defines the term “expression system” at page 7, lines 4-17, as any construct allowing the *in vivo* expression of a nucleic acid coding for a neurotrophic factor. As used in the art, the term construct refers to a particular arrangement of genetic elements in a nucleic acid. However, this term is not synonymous with the term “vector” and does not encompass vectors per se. In the claims, the term “expression system” is used synonymously with the term “vector” or to encompass the term “vector”. For example, in Claim 41

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the expression system is a vector and in Claim 42 the vectors are viral vectors and in Claim 43 the vectors are adenovirus. Given their plain meaning, one of skill in the art would not understand the term “construct” to include **vectors** of which those constructs may be a part. The metes and bounds of the claim are not clearly set forth.

Applicants argue that an expression cassette may be contained in a vector, but an expression cassette need not be a vector. However, the claims recite “expression system”, not “expression cassette.” The metes and bounds of the term “expression system” are not clearly set forth.

Claim 29 is indefinite in its recitation of “comprising two nucleic acids” because it is unclear how a single expression cassette can comprise “two nucleic acids”.

Applicants argue that Claim 29 recites an expression system comprising one neurotrophic factor-encoding region and another, different neurotrophic factor-encoding region in the nucleic acid. However, this is not at all what the claim recites. On the contrary, the claim recites “two nucleic acids.” A single expression cassette cannot comprise **two** nucleic acids. The term “an expression cassette” denotes a single molecule. A single molecule cannot comprise two molecules.

### *Conclusion*

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Baker whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Crouch, acting SPE, can be reached on (703) 308-1126. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-8724.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kay Pinkney, whose telephone number is (703) 305-3553.

Anne-Marie Baker, Ph.D.

*Anne-Marie Baker*  
ANNE-MARIE BAKER  
PATENT EXAMINER